DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 12 1999

Ref: FDA Docket No. 99V-0771
Accession Number 9520699

Ms. Connie White
Manager of Regulatory Affairs
Cell Robotics, Inc.
2715 Broadbent Parkway, NE
Albuquerque, New Mexico 87107

Dear Ms. White:

I am approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Cell Robotics, dated March 20, 1999, for a variance from the requirements of 21 CFR 1040.10(f)(3) of the Federal performance standard for laser products to incorporate a remote interlock connector. This variance will allow the introduction into commerce of the Laser Tweezer manufactured by Cell Robotics as identified in paragraph D below under the conditions stated in paragraph F.

A. Variance Number

99V0771

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated 5 years from the date of this letter.

D. Laser Product for Which Variance is Granted

This variance is granted for the Laser Tweezer.

E. Provisions From Which Variance is Granted

The variance is granted from provisions of 21 CFR 1040.10(f)(3) of the performance standard for laser products requiring that each Class IIIb and Class IV laser product have a remote interlock connector.

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All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions Under Which Variance is Granted

In lieu of the requirements referred to in item E above, the following condition shall apply to the Laser Tweezer manufactured under this variance:

> The radiation is contained within the workstation area by design, and the laser unit interlocked such that removal renders the laser inoperable.

G. Basis for Approval of Variance

CDRH has determined, in accordance with 21 CFR 1010.4(a)(1), that the laser product, the Laser Tweezer, incorporates alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard.

As an alternate for a remote interlock connector the product is designed such that the accessible radiation is contained by optics and directed toward the target. The beam cannot be directed elsewhere. Further, the unit is interlocked into the workstation such that, if removed for service, the laser is inoperable. Therefore, the product's design is believed to constitute an equivalent degree of safety as a remote interlock connector.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

> This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 99V0771 effective APR 12 1999

This variance action is available for public disclosure in the Dockets Management Branch, FDA, and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,

/S/

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health